

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0196
Inventors: Salceda et al.
Serial No.: Not Yet Assigned
Filing Date: Herewith
Examiner: Not Yet Assigned
Group Art Unit: Not Yet Assigned
Title: Method of Diagnosing, Monitoring,
Staging, Imaging and Treating Prostate
Cancer

"Express Mail" Label No: EL718096860US
Date of Deposit April 10, 2001

I hereby certify that this paper is being deposited
with the United States Postal Service "Express Mail
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Assistant Commissioner for Patents, Box PCT,
Washington, D.C. 20231.

By Deborah E. Ehret
Typed Name: Deborah Ehret

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R.
§§1.97-1.98, information relating to the above-identified
application is hereby disclosed. Inclusion of information in
this statement is not to be construed as an admission that this
information is material as that term is defined in 37 C.F.R.
§1.56(b).

- (XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.
- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
- () Certification in Accordance with §1.97(e) is set forth below; or
- () The fee of \$240.00 as set forth in §1.17(p) is attached.
- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(i)(1).
- (XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

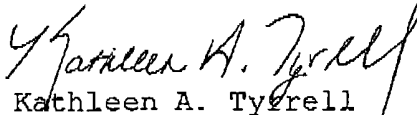
() In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____, filed _____, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

() The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,


Kathleen A. Tyrrell
Registration No. 38,350

Date: April 10, 2001

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515

Sheet 01 of 01

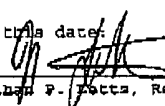
| | | | |
|---|----|---|---------------------------------------|
| Form PTO-1449 Modified List of Patents and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce | | Docket No. DEX-0196 | Serial No. Not Yet Assigned |
| | | Applicant Salceda et al. | |
| | | Filing Date Herewith | Group Not Yet Assigned |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| | AA | Bussemakers et al., "DD3:A New Prostate-specific Gene, Highly Overexpressed in Prostate Cancer ¹ ", <i>Cancer Research</i> 1999 59(23):5975-5979 | |
| | AB | Cho-Chung Y.S., "Antisense oligonucleotides for the treatment of cancer", <i>Curr. Opin. Thera. Patents</i> 1993 3(12):1737-1750 | |
| | AC | Olsson et al., "Reverse Transcriptase-Polymerase Chain Reaction Assays for Prostate Cancer", <i>Urologic Clinics of North America</i> 1997 24(2):367-378 | |
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| EXAMINER | | DATE CONSIDERED | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0196
Inventors: Salceda et al.
Serial No.: 09/807,201
Filing Date: April 25, 2001
Examiner: Unknown
Group Art Unit: 1642
Title: Method of Daignosing, Monitoring,
Staging, Imaging and Treating
Prostate Cancer

I, Nathan P. Letts, Registration No. 36,581, certify that this correspondence is being depositing with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents and Trademarks, Washington, D.C. 20231.

On this date:


Nathan P. Letts, Registration No. 36,581

12/12/2001

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

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identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

() Certification in Accordance with §1.97(e) is set forth below; or

() The fee of \$180.00 as set forth in §1.17(p) is attached.

- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(i)(1).

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() A copy of the of the PCT Search Report for @@ which corresponds to the subject US application @@ is included.

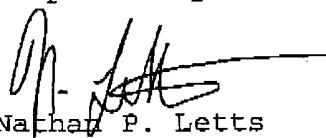
() In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were

previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____, filed _____, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

- () Due to the large size of some references, only relevant portions have been submitted. The included portions are as follows: @@ (@@). Full text of abbreviated reference is available if requested.
- () Reference @@ is in a foreign language therefore a Geneseq Patent search report is attached to demonstrate relevance.
- () The relevance of the listed references in a foreign language is as stated in the specification at pages @@.
- () All listed references are in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-0434. This form is submitted in duplicate.

Respectfully submitted,


Nathan P. Letts
Registration No. 36,581

Date: 12/17/2001

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South San Francisco, CA 94080
(650) 246-6400

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Serial Number 09/B07,201

Filing Date April 25, 2001

Applicant Salceda et al.

Group Art Unit 1642

Examiner Name Unknown

Attorney Docket Number DEX-0196

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Class | Subclass |
|--------------------|----------|-----------------|-----------------------------|---|-------|----------|
| | AA | US5514579 | 05/07/1996 | O'Hara et al. | | |
| | AB | US5952011 | 09/14/1999 | O'Hara et al. | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Class | Subclass | Translation/ Comments |
|--------------------|----------|-------------------------|-----------------------------|---|-------|----------|-----------------------|
| | AC | EP 1033401 A2 | 09/06/2000 | Dumas Milne Edwards et al. | | | |
| | AD | WO 93/13207 A2 | 07/05/1993 | O'HARA et al. | | | |
| | AE | WO 98/20165 A2 | 05/14/1998 | LANDER et al. | | | |
| | AF | WO 99/37811 A1 | 07/29/1999 | AN et al. | | | |
| | AG | WO 00/04149 A2 | 01/27/2000 | DILLON et al. | | | |
| | AH | WO 00/14234 A1 | 03/18/2000 | AN et al. | | | |
| | AI | WO 00/23111 A1 | 04/27/2000 | SALCEDA et al. | | | |
| | AJ | WO 01/25272 A2 | 04/12/2001 | XU et al. | | | |
| | AK | WO 01/34802 A2 | 05/17/2001 | XU et al. | | | |
| | AL | WO 01/51633 A2 | 07/19/2001 | XU et al. | | | |

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

| | |
|------------------------|----------------|
| Serial Number | 09/807,201 |
| Filing Date | April 25, 2001 |
| Applicant | Salceda et al. |
| Group Art Unit | 1842 |
| Examiner Name | Unknown |
| Attorney Docket Number | DEX-0196 |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. | Author, title of the article, title of the item, date, volume-issue number, page(s). | Translation/ Comments |
|---------------------|----------|--|-----------------------|
| | AM | An G, Meka CS, Bright SP, Valtri RW. Human prostate-specific transglutaminase gene: promoter cloning, tissue-specific expression, and down-regulation in metastatic prostate cancer. <i>Urology</i> . 1999 Dec;54(6):1105-11. | |
| | AN | Dubbink HJ, Cleutjens KB, van der Korput HA, Trapman J, Romijn JC. An Sp1 binding site is essential for basal activity of the human prostate-specific transglutaminase gene (TGM4) promoter. <i>Gene</i> . 1999 Nov 29, Vol.240(2), pages 261-7. | |
| | AO | Dubbink HJ, Hoedemaeker RF, van der Kwast TM, Schroder FH, Romijn JC. Human prostate-specific transglutaminase: a new prostatic marker with a unique distribution pattern. <i>Lab Invest</i> . 1999 Feb, Vol. 79(2), pages 141-50. | |
| | AP | Dubbink, H.J., de Waal, L., van Haperen, R., Verkalk, N.S., Trapman, J. and Romijn, J.C. The human prostate-specific transglutaminase gene (TGM4): genomic organization, tissue-specific expression, and promoter characterization. <i>Genomics</i> , Vol. 51(3), 1998, pages 434-444. | |
| | AQ | Dubbink, H.J., Verkalk, N.S., Faber, P.W., Trapman, J., Schroder, F.H. and Romijn, J.C. Tissue specific and androgen-regulated expression of human prostate-specific transglutaminase. <i>Biochem. J.</i> Vol. 315(Pt 3), 1996, pages 901-908. | |
| | AR | Gentile V, Grant FJ, Porta R and Baldini A. Localization of the human prostate transglutaminase (type IV) gene. (TGM4) to chromosome 3p21.33-p22 by fluorescence in situ hybridization. <i>Genomics</i> , Vol.27(1), 1995, pages 219-220. | |
| | AS | Goebel HW, Rausch U, Steinhoff M, Seitz J, Bacher M, Papotti M, Bussolati G, Tuohimaa P, Aumuller G. Arguments against the prostatic origin of the R-3327 Dunning H tumor. <i>Virchows Arch B Cell Pathol Incl Mol Pathol</i> . 1992, Vol.62(1), pages 9-18. | |
| | AT | Grant FJ, Taylor DA, Sheppard PO, Mathewes SL, Lint W, Vanaja E, Bishop PD and O'Hara PJ. Molecular cloning and characterization of a novel transglutaminase cDNA from a human prostate cDNA library. <i>Biochem. Biophys. Res. Commun.</i> Vol.203(2), 1994, pages 1117-1123. | |

Examiner
Signature

Date
Considered


*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0196
Inventors: Salceda et al.
Serial No.: 09/807,201
Filing Date: 25 April 2001
Examiner: Unknown
Group Art Unit: 1642
Title: Method of Diagnosing, Monitoring,
Staging, Imaging and Treating
Prostate Cancer

I, Nathan F. Letts, Registration No. 36,581, certify that this correspondence is being depositing with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents and Trademarks, Washington, D.C. 20231.

On this date: June 13, 2002


Nathan F. Letts, Registration No. 36,581

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

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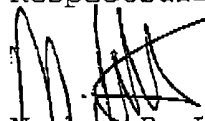
previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____, filed _____, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

(XX) Due to the large size of some references, only relevant portions have been submitted. The included portions are as follows: WO WO 98/45435 A2 (Pages 1-44, 53, 56-92, 505-506, 590-631); WO 99/06548 A2 (Pages 1-148, Figs 1-4, Sequence Listing 1, SL 343-346). Full text of abbreviated reference is available if requested.

() Reference @@ is in a foreign language. Therefore, a Geneseq Search report is attached to demonstrate relevance.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-0434. This form is submitted in duplicate.

Respectfully submitted,



Nathan P. Letts
Registration No. 36,581

Date: June 13, 2002

DiaDexus, Inc.
343 Oyster Point Blvd.
South San Francisco, CA 94080
(650) 246-6400

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Serial Number 09/807,201

Filing Date 25 April 2001

Applicant Salceda et al

Group Art Unit 1642

Examiner Name Unknown

Attorney Docket Number DEX-0196

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Class | Subclass | Filing Date MM-DD-YYYY |
|--------------------|----------|-----------------|-----------------------------|---|-------|----------|------------------------|
| | | | | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Class | Subclass | Translation/ Comments |
|--------------------|----------|-------------------------|-----------------------------|---|-------|----------|-----------------------|
| | AA | WO 98/45435 A2 | 10/15/1998 | Jacobs et al. | | | Abbreviated |
| | AB | WO 99/06548 A2 | 2/11/1999 | Dumas Milne Edwards et al. | | | Abbreviated |
| | AC | WO 99/57132 A1 | 11/11/1999 | Jacobs et al. | | | |
| | AD | WO 00/12706 A1 | 03/09/2000 | Pastan et al. | | | |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Author, title of the article, title of the item, date, volume-issue number, page(s). | Translation/ Comments |
|--------------------|----------|---|-----------------------|
| | AE | Brinkmann et al. <i>PAGE-1</i> , an X chromosome-linked <i>GAGE</i> -like gene that is expressed in normal and neoplastic prostate, testis, and uterus. PNAS. Sept 1998;95:10757-10762. | |
| | AF | Chen et al. Isolation and characterization of <i>PAGE-1</i> and <i>GAGE-7</i> . JBC. 10 July 1998;273(28):17618-17625. | |
| | AG | Dannull et al. Prostate stem cell antigen is a promising candidate for immunotherapy of advanced prostate cancer. Can. Res. 1 Oct 2000;60(19):5323-5598. | |

Examiner
SignatureDate
Considered

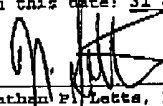
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0196
Inventors: Salceda et al.
Serial No.: 09/807,201
Filing Date: 25 April 2001
Examiner: Davis, M T
Group Art Unit: 1642
Title: Method of Diagnosing, Monitoring,
Staging, Imaging and Treating
Prostate Cancer

I, Nathan P. Letts, Registration No. 36,581, certify that this correspondence is being depositing with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents and Trademarks, Washington, D.C. 20231.

On this date: 31 July 2002


Nathan P. Letts, Registration No. 36,581

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

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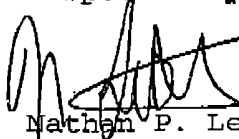
previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____, filed _____, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

(xx) Due to the large size of some references, only relevant portions have been submitted. The included portions are as follows: WO 00/55351 A1 (Pages 1-13, 73, 89-95, 134-150, 168-401, 465-469, Sequence Listing 1, SL 484-486, International Search Report); WO 00/735454 A1 (pages 1-591, figures 207-208, ISR). Full text of abbreviated reference is available if requested.

() Reference @@ is in a foreign language. Therefore, a Geneseq Search report is attached to demonstrate relevance.

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Respectfully submitted,



Nathan P. Letts
Registration No. 36,581

Date: 31 July 2002

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Serial Number

06-07,201

Filing Date

25 April 2001

Applicant

Salceda et al

Group Art Unit

1642

Examiner Name

Davis, M T

Attorney Docket Number

DEX-0196

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|----------|-----------------|-----------------------------|---|-------|----------|------------------------|
| Examiner Initials * | Cite No. | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Class | Subclass | Filing Date MM-DD-YYYY |
| | AA | 6,043,033 | 03/28/2000 | Bandman et al. | | | 02/27/1997 |
| | AB | 6,203,979 | 03/20/2001 | Bandman et al. | | | 01/16/1998 |
| | AC | 6,262,245 | 07/17/2001 | Xu et al. | | | 02/25/1998 |
| | AD | 6,294,663 | 09/25/2001 | O'Brien et al. | | | 03/02/2000 |
| | AE | 6,350,448 | 02/26/2002 | Bandman et al. | | | 01/07/2000 |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|----------|-------------------------|-----------------------------|---|-------|----------|-----------------------|
| Examiner Initials * | Cite No. | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Class | Subclass | Translation/ Comments |
| | AF | JP 11032768 A2 | 02/09/1999 | Hiroshi et al. | | | No Trans/ Front Page |
| | AG | WO 98/36054 A1 | 08/20/1998 | Antalis et al. | | | |
| | AH | WO 98/37093 A2 | 08/27/1998 | Xu et al. | | | |
| | AI | WO 98/37418 A2 | 08/27/1998 | Xu et al. | | | |
| | AJ | WO 99/14328 A2 | 03/25/1999 | Wood et al. | | | |
| | AK | WO 99/36550 A2 | 07/22/1999 | Bandman et al. | | | |
| | AL | WO 99/60162 A1 | 11/25/1999 | Ali et al. | | | |
| | AM | WO 99/62941 A2 | 12/09/1999 | Afar et al. | | | |
| | AN | WO 99/62942 A2 | 12/09/1999 | Afar et al. | | | |
| | AO | WO 00/00605 A1 | 01/06/2000 | Wong et al. | | | |
| | AP | WO 00/12758 A1 | 03/09/2000 | Salceda et al. | | | |
| | AQ | WO 00/18805 A1 | 03/30/2000 | Ali et al. | | | |
| | AR | WO 00/18961 A2 | 04/06/2000 | Macbeth et al. | | | |
| | AS | WO 00/29448 A2 | 05/25/2000 | Kato et al. | | | |
| | AT | WO 00/36107 A2 | 06/22/2000 | Mitcham et al. | | | |
| | AU | WO 00/43495 A2 | 07/27/2000 | Rosen et al. | | | |
| | AV | WO 00/55351 A1 | 09/21/2000 | Rosen et al. | | | Abbreviated |
| | AW | WO 00/55629 A2 | 09/21/2000 | Mack et al. | | | |
| | AX | WO 00/73454 A1 | 12/07/2000 | Ashkenazi et al. | | | Abbreviated |
| | AY | WO 00/76531 A1 | 12/21/2000 | Rosen et al. | | | |
| | AZ | WO 00/78960 A2 | 12/28/2000 | Yuqiu et al. | | | |
| | BA | WO 01/04311 A1 | 01/18/2001 | Ashkenazi et al. | | | |
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| | BD | WO 01/27257 A1 | 04/19/2001 | O'Brien et al. | | | |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
|---|----------|--|-----------------------|
| Examiner Initials * | Cite No. | Author, title of the article, title of the item, date, volume-issue number, page(s). | Translation/ Comments |
| | BE | Paoloni-Giacobino et al. Cloning of the TMPRSS2 gene, which encodes a novel serine protease with transmembrane, LDLRA, and SRCR domains and maps to 21q22.3, Genomics, 1997; 44:309-320. | |
| | BF | Pasquall et al. Changes in tissue transglutaminase activity and expression during retinoic acid-induced growth arrest and apoptosis in primary cultures of human epithelial prostate cells. J Clin Endocrin & Metab. 1999;84(4):1463-1469. | |

Examiner Signature

Date Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0196
Inventors: Salceda et al.
Serial No.: 09/807,201
Filing Date: April 25, 2001
Examiner: Minh Tam B Davis
Group Art Unit: 1642
Title: Method of Diagnosing, Monitoring,
Staging, Imaging and Treating Prostate
Cancer

I, Kathleen A. Tyrrell, Registration No. 38,350, certify that this correspondence is being depositing with the U.S. Postal Service as First Class mail in an envelope addressed to the U.S. Patent and Trademark Office, Box 2327, Arlington, VA 22202

On this date: January 23, 2003

Kathleen A. Tyrrell, Registration No. 38,350

U.S. Patent and Trademark Office
Box 2327
Arlington, VA 22202

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified

application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

() Certification in Accordance with §1.97(e) is set forth below; or

() The fee of \$180.00 as set forth in §1.17(p) is attached.

- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I)(1).

- (XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

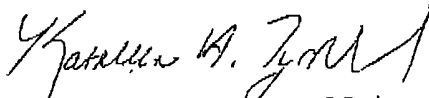
- () In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____, filed _____, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- () The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,



Kathleen A. Tyrrell
Registration No. 38,350

Date: January 23, 2003

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Sheet 01 of 01

| | | | |
|---|---|-------------------------------|--------------------------|
| Form PTO-1449 Modified List of Patents and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce | | Docket No. DEX-0196 | Serial No. 09/807,201 |
| | | Applicant Salceda et al. | |
| | | Filing Date April 25, 2001 | Group 1642 |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| CA | Blok et al., "Isolation of cDNAs That Are Differentially Expressed Between Androgen-Dependent and Androgen-Independent Prostate Carcinoma Cells Using Differentially Display PCR", The Prostate 1995 26:213-224 | | |
| CB | Chang et al., "Differentially Expressed Genes in Androgen-dependent and -independent Prostate Carcinomas ¹ ", Cancer Research 1997 57:4075-4081 | | |
| CC | Friedrich et al., "Differentiation-Stage Specific Expression of Oncoprotein 18 in Human and Rat Prostatic Adenocarcinoma", The Prostate 1995 27:102-109 | | |
| CD | Gagnon et al., "Expression of Zn-Alpha ² -Glycoprotein and PSP-94 in Prostatic Adenocarcinoma", American Journal of Pathology 1990 136(5):1147-1152 | | |
| CE | Hale et al., "Zinc α -2-Glycoprotein Is Expressed by Malignant Prostatic Epithelium and May Serve as a Potential Serum Marker for Prostate Cancer ¹ ", Clinical Cancer Research 2001 7(7):846-853 | | |
| CF | López-Otín et al., "Breast and Prostate Cancer: An Analysis of Common Epidemiological, Genetic and Biochemical Features", Endocrine Reviews 1998 19(4):365-396 | | |
| CG | Olsson et al., "Reverse Transcriptase-Polymerase Chain Reaction Assays for Prostate Cancer", Urologic Clinics of North America 1997 24(2):367-378 | | |
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| CI | EMBL/GenBank/DBJ X0-002220465 -Ueyama et al., "Molecular Cloning and Chromosomal Assignment of the Gene for Human Zn- α_2 -glycoprotein", Biochemistry 1993 32:12968-12976 | | |
| EXAMINER | | DATE CONSIDERED | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0196
Inventors: Salceda et al.
Serial No.: 09/807,201
Filing Date: April 25, 2001
Examiner: Minh Tam B Davis
Group Art Unit: 1642
Title: Method of Diagnosing, Monitoring,
Staging, Imaging and Treating Prostate
Cancer

I, Kathleen A. Tyrrell, Registration No. 38,350,
certify that this correspondence is being deposited
with the U.S. Postal Service as First Class mail in
an envelope addressed to the Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

On this date: May 12, 2003


Kathleen A. Tyrrell, Registration No. 38,350

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R.
§§1.97-1.98, information relating to the above-identified
application is hereby disclosed. Inclusion of information in
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(XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

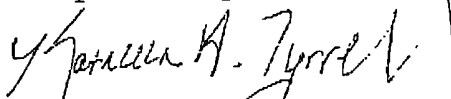
() In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____, filed _____, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

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() The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,



Kathleen A. Tyrrell
Registration No. 38,350

Date: May 19, 2003

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Marlton, New Jersey 08053

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Sheet 01 of 02

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|---|---|-------------------------------|--------------------------|
| Form PTO-1449 Modified | | Docket No. DEX-0196 | Serial No. 09/807,201 |
| List of Patents and Publications Cited by Applicant (Use several sheets if necessary) | | Applicant Salceda et al. | |
| | | Filing Date April 25, 2001 | Group 1642 |
| U.S. Department of Commerce | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | |
| DA | Afar et al., "Catalytic Cleavage of the Androgen-regulated TMPRSS2 Protease Results in Its Secretion by Prostate and Prostate Cancer Epithelia", Cancer Research 2001 61:1686-1692 XP-002229964 | | |
| DB | Lin et al., "Prostate-localized and Androgen-regulated Expression of the Membrane-bound Serine Protease TMPRSS2 ¹ ", Cancer Research 1999 59:4180-4184 XP-000929801 | | |
| DC | Jacquinet et al., "Homo sapiens epitheliasin (TMPRSS2) mRNA, complete cds." 2001 Accession No. AF329454 XP-002229966 | | |
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| EXAMINER | | DATE CONSIDERED | |

Sheet 02 of 02

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|---|-------------------------------|--------------------------|
| Form PTO-1449 Modified List of Patents and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce | Docket No. DEX-0196 | Serial No. 09/807,201 |
| | Applicant Salceda et al. | |
| | Filing Date April 25, 2001 | Group 1642 |

U. S. PATENT DOCUMENTS

| Examiner Initial | Document No. | Date | Name | Class | Subclass |
|---------------------|-----------------|------|------|-------|----------|
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FOREIGN PATENT DOCUMENTS

| Examiner Initial | Document No. | Date | Country | Translation YES NO |
|---------------------|--------------|----------|---------|-----------------------|
| EA | WO 99/67384 | 29-12-99 | PCT | x |
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